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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,504	10/19/2001	Steven J. Siegel	PENN-0789	3358

7590 02/10/2004  
Licata & Tyrrell P.C.  
66 E. Main Street  
Marlton, NJ 08053

EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 02/10/2004

6

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/046,504

Applicant(s)

SIEGEL ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 07/01/02.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

Examiner acknowledges receipt of IDS filed 07/01/02, declaration and request for extension of time filed 06/25/02. Examiner acknowledges claim for benefit of priority for Provisional application no. 60/242,304

#### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for acetone, does not reasonably provide enablement for all organic solvents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The following Wands factors are considered:

1. The quantity of experimentation necessary

Acetone is the only organic solvent that is disclosed in applicants' specification.

Applicants have not provided a list of organic solvents that can be used to dissolve the polymer and haloperidol and on the last line of page 9 and line 4 of page 14; applicants disclosed acetone as the organic solvent. Since the specification failed to list other solvents suitable for the haloperidol-lactide-glycolide system and since applicants claim solvent, which encompasses a whole list of solvent, it would require the person of ordinary skill in the art or the skilled artisan to test allot of organic solvents to ascertain those solvents that are suitable for the haloperidol-lactide-glycolide system and this

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exercise in the amount or quantity of experimentation would be unreasonable and of undue burden to one of ordinary skill or one of skill in the art.

2. The amount of direction or guidance presented

Applicants' specification provided guidance only to acetone as the organic solvent.

3. The predictability or unpredictability

Since applicants' specification does not provide solvents other than acetone, there is lacking information on how the haloperidol-lactide-glycolide system will behave in organic solvents other than acetone.

4. The breadth of the claims

The scope of the claims is not commensurate with the disclosure because the specification enables acetone as the solvent and does not provide direction as to other solvents. The person of ordinary skill would be required to perform undue experimentation to determine all the organic solvents that would work with the haloperidol-lactide-glycolide system.

It is suggested that the claim recite the organic solvent that is enabled by the specification.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Kino et al. (WO 94/10982, cited in applicants' specification, abstract).

Kino discloses an implantable system that comprises haloperidol and lactic acid/glycolic acid copolymer (abstract). Kino meets the limitations of the claims.

5. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Cheng et al. (J. Controlled Release, 1988, 203-212, cited by applicants on form PTO 1449).

Cheng discloses a delivery system that comprises haloperidol and 50:50 lactide-glycolide copolymer (section 2.1). Cheng loads haloperidol onto lactide-glycolide copolymer in the presence of the organic solvent, dichloromethane, emulsifies the mixture and the solvent is evaporated off to produce microspheres (section 2.2). Cheng discloses in the introduction that haloperidol is useful in the treatment of schizophrenia. "Surgically implantable" in claim 1 is a future intended use and future intended carries no patentable weight in a composition claim. It is not critical how a composition is made. Thus, Cheng meets the limitations of the claims.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 4-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. ((J. Controlled Release, 1988, 203-212, cited by applicants on form PTO 1449) in view of Kino (WO 94/10982, cited in applicants' specification, abstract).

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Cheng discloses the method of the instant claims. Cheng does not however disclose formulating the haloperidol microspheres into an implant. However, Kino discloses that a system that comprises haloperidol and lactide-glycolide copolymer is implantable. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the haloperidol microspheres according to the teachings of Cheng. One having ordinary skill in the art would have been motivated to formulate the microspheres into an implantable device according to Kino with the expectation of facilitating the delivery of haloperidol delivery with little pain.


8. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 242-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara   
Patent Examiner  
Tech. Center 1600